REMARKS

Applicants have further amended the claims to more particularly define the invention in view of the outstanding Official Action. A notice of appeal has also been filed to provide the Examiner with sufficient time to consider this response which is believed to place the application in condition for allowance or at least better condition for appeal. Each of the independent claims has been amended to add the limitation that the alloy does not contain an intentionally added element selected from the Pt group. This is believed to be the addition of an implicit limitation to the claims and as such does not create a new issue. Entry of the amendment is in order and is most respectfully requested.

The rejection of claims 9, 10, 11 and 14 under 35 USC102(b) as being anticipated by JP'744 has been carefully considered but is most respectfully traversed in view of the amendment to the claims and the following comments. In the rejection, it is urged that the prior art teaches a method of improving the castability of a titanium alloy and refers to page 2 claim 1. However, this portion of the reference refers to a titanium alloy having good crevice corrosion resistance but makes no reference to castability. Good corrosion resistance would not be understood as having good castability by one of ordinary skill in the art and is a claimed limitation not found in the prior art. The purpose of the prior art reference is to obtain Ti alloy with improved crevice corrosion and the essential element, in addition to Ti, is a Pt group element. On the contrary, the presently claimed invention is directed to a technique to improve the castablilty of titanium alloy and the essential element is Bi.

Further, newly amended claims do not contain a Pt element and clearly exclude it. How can one of ordinary skill in the art conceive the presently claimed invention from the teaching of the primary reference. Is there a teaching as to the relationship

between the "crevice corrosion" and "castability" of the titanium alloy. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants submit herewith two certificates of the product which clearly indicate at no Pt element is present.

The rejection of Claims 1-3, 6-8, 15-17 and 20-24 and 15-22 under 35 U.S.C. 103(a) as being unpatentable over JP'744 in view of Prasad (US Pat. No. 5,091,148) with evidence from Connie Daughtry has been carefully considered but is most respectfully traversed. It is urged in the Official Action that JP'744 discloses a method of improving the castability of a titanium alloy substantially as claimed. As noted above, this statement is specifically traversed. Moreover, the necessary motivation to combine the teachings and arrive at the presently claimed invention is not present in the prior art.

It is recognized in the rejection that JP'744 does not disclose wherein the alloy is in the form of a medical device. Prasad discloses an **analogous** (emphasis added) titanium alloy for forming a medical device (e.g., a dental casting, see abstract). Where is there any teaching that the compositions are analogous and one of ordinary skill in the art would be motivated to combine the teachings? Obvious to try is not the standard of obviousness under 35 USC 103.

The present invention relates to a medical device made of a biocompatible titanium alloy having improved castability and a method to improve the castability of a titanium alloy. Thus, as a threshold matter, JP'744 does not disclose the invention substantially as claimed because this reference is directed to titanium alloy which has superior crevice corrosion resistance and no utility for the composition is described. Castability is the ability of casting, where casting is defined as 1) an object at or near finished shape obtained by solidification of a substance in a mold or 2) pouring molten metal into a mold to produce an object of desired shape.

The present invention focuses on improving castability by way of introducing Bi into the Ti alloy. Improved castability is also beneficial since a cost-effective way to

manufacture Ti alloys is by near-shape casting which requires little or no machining. Ti alloys are inherently difficult to cast due to their high melting temperatures and high chemical reactivity. The present invention provides a simple and effective method to improve castability.

Because titanium is inherently difficult to cast due to its high melting point and high reactivity, the present invention is directed to a medical device having improved castability consisting essentially of a titanium alloy and a method to improve a titanium alloy wherein the castability is greatly improved. Applicants have discovered that the introduction of Bismuth in certain amounts to various titanium alloys achieves the goal of improved castability. Such improvement can clearly be seen by referring to the comparative examples summarized in Table 1 of the application. When bismuth was melted into the various titanium samples, the castability was improved over the same titanium sample without the bismuth. Applicants further discovered that the addition of more bismuth to the titanium alloys caused the improved castability to decrease, although the castability was still improved with reference to the titanium alloy containing no bismuth.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The present invention claims a medical device made of a biocompatible titanium alloy composition having an improved castability consisting essentially of about 0.01-5

wt% Bi based on the weight of the alloy composition; at least one alloy element selected from a group consisting of Mo, Nb, Ta, Zr and Hf; and the balance Ti.

The transitional phrase "consisting of" excludes any element, step or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). Thus, the Kimura reference, which uses the transitional phrase "consisting of" in both the claims and the specification, is limited to teaching only that which is specifically identified in the embodiments set forth in the disclosure and claims. Accordingly, in order to support a §103(a) rejection, JP'744 must be modified by a motivational statement or suggestion that explains why it would be obvious to one having ordinary skill in the art to add and/or remove elements specifically required by the closed language of the claims and specification. The Office Action has not provided a motivation or suggestion as to why it would have been obvious to one of ordinary skill in the art to use the alloy with a noble metal.

Further, as mentioned above, a §103(a) rejection is only proper when the reference teaches or suggests all of the claim limitations. The Prasad reference requires a noble metal in the medical device not required by the presently claimed invention.

Section 2143.03 of the MPEP states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

With respect to claim 15, it is urged that JP'744 that further discloses a method of making an article using a titanium alloy consisting essentially of 0.01-5wt% Bi (e.g., 0.05-2.00 % Bi, see the constitution portion of the abstract), at least one alloy selected from the group consisting of Mo, Nb, Ta, Zr, and Hf (e.g., Nb, Ta, Zr, and Hf, see the abstract), and the balance Ti. JP'744 fails to specify a method of making a medical device including casting the titanium alloy. Prasad discloses a method of making a

medical device (e.g., a dental casting, see the abstract) by casting using an analogous titanium alloy. It would have been obvious to modify the method of JP'744 so as to have formed a medical device by casting as suggested by Prasad since Prasad discloses that an analogous titanium alloy can be used in a method for forming a medical device using an analogous titanium alloy. This aspect of the rejection is specifically traversed in view of the above comments.

With respect to claim 17, it is urged in the Official Action that JP'744 discloses a method of making an article using a titanium alloy consisting essentially of 0.01-5wt% Bi (e.g., 0.05-2.00 % Bi, see the constitution portion of the abstract), at least one eutectoid beta stabilizing agent selected from the group consisting of Mo, Nb, Ta, Zr, and Hf (e.g., Nb Ta, Zr, and Hf, see the abstract), at least one eutectoid beta stabilizing agent selected from the group consisting of Fe, Cr, Mn, Co, Ni, Cu, Ag, Pd, Si, and Sn (e.g., the Pt group elements including Ag, Au, and Pd, see the constitution portion of the abstract), and the balance Ti. JP'744 fails to specify a method of making a medical device including casting the titanium alloy. Prasad discloses a method of making a medical device (e.g., a dental casting, see the abstract) by casting using an analogous titanium alloy. It would have been obvious to modify the method of JP'744 so as to have formed a medical device by casting as suggested by Prasad since Prasad discloses that an analogous titanium alloy can be used in a method for forming a medical device using an analogous titanium alloy. This aspect of the rejection is specifically traversed in view of the above comments.

With respect to claims 23 and 24 it is urged that the primary reference discloses a method substantially as claimed and the Examiner asserts that titanium has natural iron impurities when separated from the ore. However, there is no disclosure of this in the primary reference which details the content of the alloy described therein. This is most respectfully submitted to be relying on applicants' teaching and is impermissible hindsight. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and amendments to the claims an early and favorable action on the application is now in order and is most respectfully requested.

Respectfully submitted,

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A03.wpd

April 2, 2007

INSPECTION CERTIFICATE

Messers: 三川金屬有限公司 06-2827555	Date of Issue: Apr. 18, 2006
	Certificate No.: ML06-016
	Contract No.:

Commodity	Specification	Manufacturer No.
Titanium Round Bar	ASTM B348 Gr2	5P9449

Size (mm)	Quantity	Heat No.	Condition
25 ϕ x 1000	1 pcs		

Chemical Composition (% maximum)

H x10000	O x 100	N x 100	Fe x 100	C x 100	Residuals each			Ti
					each	total		
2	14	1	8	1				Bal

Mechanical Properties

Yield Strength 0.2% KSI	Tensile Strength KSI	Elongation %
45	71	26

Remarks

WE HEREBY CERTIFY THAT THE MATERIAL DESCRIPTION HEREIN HAS BEEN MADE IN ACCORDANCE WITH THE RULES OF THE CONTRACT.

三川金屬有限公司 收發章 TEL:06-2827123 FAX:06-2827555

Certificate of Analysis

THE RIGHT CHEMICALS
THE RIGHT CHEMISTRY®

Molybdenum wire, 1.0mm (0.04in) dia, annealed, 99.95% (metals basis)

Stock Number: 10039
Lot Number: G12R011

Analysis

Al	< 8	C	< 10
Ca	< 2	Cr	12
Cu	< 8	Fe	12
Mg	< 2	Mn	< 3
Ni	20	Si	< 15
Sn	< 15	Pb	< 10
Na	< 5	K	21
W	140	N_2	14
O_2	< 10		

Values given in ppm unless otherwise noted

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